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| 10/630,885 | 07/30/2003 | Karla Weaver | 10142/01601 | 7939 |
| 30636 7590 12/08/2008 FAY KAPLUN & MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038 | | | | |
| EXAMINER STIGELL, THEODORE J | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/630,885

Applicant(s)

WEAVER ET AL.

Examiner

THEODORE J. STIGELL

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-26 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-19 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Drawings

The drawings were received on 2/14/2008. These drawings are accepted.

Claim Rejections - 35 USC § 112

The 35 USC 112 rejections have been withdrawn in light of the amendments filed on 2/14/2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-17 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (4,244,379). Smith discloses a valve apparatus (110) for medical applications comprising a first flexible disk (130) extending across a first lumen (114) through which a flow of materials is to be controlled, the first flexible disk including a plurality of first movable elements (either side of slit) formed on opposite sides of at least one slit (132) extending through the first flexible disk, the first moveable members being biased so that when a pressure from naturally occurring blood pressure is applied to the disk the valve remains closed and when a pressure exerted by an outside pump is applied to the disk the valve opens to allow fluid to flow (see column 5, lines 34-57), wherein the slit is substantially linear and parallel to the axis of the disk, further

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comprising a housing (112) coupled to a catheter (122) with a sharpened distal tip for insertion into the lumen of a body, further comprising a biasing member (140) coupled to the first flexible disk and substantially parallel to the first slit, and wherein the first flexible disk is formed of silicone and is permanently sealed around the entire perimeter of the disk.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7, 9-17, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (5,324,274) in view of Smith (4,244,379). Martin discloses a dual lumen catheter with two valve housings (42, 44) with rotary valves. Martin does not disclose a pressure actuated valve assembly. Smith discloses a pressure actuated valve assembly that only opens when the pressure in the patient is greater than in the vessel into which the fluid is being drawn. The Smith valve configuration is effective is

preventing unwanted leakage and re-injection of the withdrawn fluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the valve assembly of Martin with the valve configuration of Smith to avoid leakage and re-injection of fluid that can be caused by human error associated with rotary valves (mistakenly leaving the rotary valve open).

Claims 8 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (5,324,274) and Smith (4,244,379) in further view of Jones (2,720,881). Martin and Smith together disclose all of the limitations recited in claims 3 and 15. However, they do not disclose a pair of second perpendicular slits intersecting the first slit. Jones teaches such a configuration and teaches that this configuration is useful in pressure actuated valves. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Martin and Smith with the valve configuration of Jones to make an improved pressure actuated valve.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 and 23-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 7,435,236. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations do not pass the threshold for patentability.

Response to Arguments

Applicant's arguments filed 2/14/2008 have been fully considered but they are not persuasive.

Smith (4,244,379)

In response to the applicant's argument that Smith fails to disclose the limitations recited in claims 15 and 26, the examiner respectfully disagrees. The applicant argues that Smith does not disclose a device that is capable of performing dialysis and therefore does not disclose a dialysis connector or a flow shutoff device for dialysis applications. The examiner maintains that these limitations are broad and functional and that the device of Smith could be used in a dialysis application even though it was not specifically designed for that purpose. The issue at hand is not whether Smith discloses dialysis applications but if the device of Smith could be used at all in a dialysis application. The applicant seems to provide support to the examiner's argument in paragraph [0014] of the published application (US 2005/0027261). The applicant

appears to disclose that the application (dialysis) is not a critical feature of the device and that the device can be modified for other applications. It therefore seems that the recited structure of the device, and not the application, is the novel feature. The examiner maintains that Smith discloses all of the recited structural features and therefore the rejection has been maintained.

Martin (5,324,274) in view of Smith (4,244,379)

In response to the applicant's argument that the proposed modification would be detrimental to the device, the examiner respectfully disagrees. The examiner maintains that one of ordinary skill in the art would recognize that the valves would have to be placed in a normal and reversed configuration as the applicant points out on page 14 of the Remarks. However, the applicant then argues that this configuration would not work because there would be no source of vacuum to open the valve placed in the reverse configuration because that would result in a vacuum placed in the body. The examiner agrees with the applicant that it would be unreasonable to place a vacuum in the body of a patient but maintains that the vacuum discussed in Smith is only an example of a way to open the valve. The valves are disclosed by Smith as being designed "with a thickness sized so as to selectively determine the force necessary to force open the slit 32 with fluid pressure" (see column 3, lines 23-27). It is clear that the valves can be designed to open based on any fluid pressure including the pressure of blood leaving and returning to a patient as is disclosed in Martin. The examiner maintains that the combination is proper and that the proposed modification will not destroy the device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763